STATE OF VERMONT GREEN MOUNTAIN CARE BOARD

In re:	Application of the University of Vermont Medical)	
	Center to Expand, Consolidate, and Automate Outpatient)	
	Pharmacy Processing Operations at Holly Court)	GMCB-022-21con
)	

DECISION AND ORDER

Introduction

In this Decision and Order, we review the application of the University of Vermont Medical Center (UVMMC or applicant) for a certificate of need (CON) to expand, consolidate, and automate outpatient pharmacy processing operations at 75 and 79 Holly Court in Williston, Vermont. The total capital cost of the project is \$5,810,888. For the reasons set forth below, we approve the application and issue the applicant a CON, subject to the conditions set forth therein.

Procedural Background

On November 17, 2021, UVMMC applied for a CON to expand, consolidate, and automate pharmacy processing operations at 75 and 79 Holly Court in Williston, Vermont. UVMMC also requested expedited review of its application, which the Board granted on November 19, 2021.

Beginning December 3, 2021, the Board requested, through a series of three sets of interrogatories, that the applicant provide additional or clarifying information. The applicant responded to the third and final interrogatory on March 14, 2022.

On December 16, 2021, the Vermont Office of the Health Care Advocate (HCA), representing the interests of Vermont health care consumers, intervened in the proceedings.

The application was closed on March 21, 2022. The HCA waived a hearing pursuant to 18 V.S.A. § 9440(c)(5)(C)(i) and no hearing was held.

Jurisdiction

The Board is responsible for administering the certificate of need program pursuant to 18 V.S.A. § 9375(b)(8) and 18 V.S.A. § 9433. The project as proposed by the applicant is subject to certificate of need review under 18 V.S.A. § 9434(b)(1).

Findings of Fact

1. UVMMC currently operates an outpatient pharmacy that predominantly serves University of Vermont Health Network (UVMHN) patients and UVMHN employees and their family members. *See* Application (App.), 2.

- 2. UVMMC's outpatient pharmacy mail order and retail dispensing operations are currently housed in leased space at 1 South Prospect Street (UHC) in Burlington, Vermont, while its outpatient specialty pharmacy processing operations are located at 75 and 79 Holly Court in Williston, Vermont. *See* App., 1.
- 3. UVMMC projects that outpatient pharmacy volumes will grow substantially over the next three years due to increasing mail order and specialty drug demand, the evolution of the Health Assistance Program (HAP), and the expansion of a Pharmacy Benefits Management (PBM) program. *See* App., 2. Specifically, UVMMC projects that volumes will grow from 101,099 scripts in fiscal year 2020 (approximately 398 per day on average) to 220,059 scripts in fiscal year 2025 (approximately 866 per day on average), with growth primarily in specialty and mail order scripts. *See* App., 3; Response to Questions (Resp.) (Mar. 14, 2022), 2.
- 4. The HAP is an existing program in place at some UVMHN hospitals that enables qualified low- and middle-income patients to receive their prescription medications at no cost. There is an initiative to continue expanding the HAP to additional UVMHN affiliates. The program's target volume is 27,000 mail order and 3,000 specialty prescriptions annually. A three-year growth model has been developed and is in the early stages of rollout. *See* App., 2.
- 5. UVMHN sponsors a self-funded health plan that is already available to UVMMC employees. *See* App., 2. The plan includes prescription drug coverage through a pharmacy benefit manage that incentivizes employees to fill their outpatient prescriptions by mail order at UVMHN pharmacies. For example, the plan requires members to fill all specialty prescriptions with the UVMMC specialty pharmacy and includes a zero-dollar copay for most generic prescriptions when filled by the UVMMC pharmacy. App., 3. UVMHN affiliates Porter Medical Center and Home Health and Hospice joined the UVMHN self-funded health plan at the start of 2021, and Central Vermont Medical Center and the non-union employees of Alice Hyde Medical Center, Elizabethtown Community Hospital, and Champlain Valley Physicians Hospital will join in 2022. UVMMC expects that the plan's coverage will be expanded to UVMHN's remaining workforce over the next several years. App. 3.
- 6. The project will co-locate mail order and specialty pharmacy processing operations at Holly Court and automate drug dispensing operations. *See* Letter of Intent (LOI), 2; App., 1. UVMMC will continue to offer limited retail pharmacy services at UHC. App., 1. There will continue to be no retail presence at the Holly Court site. *See* App., 1, 4.
- 7. The project will create a single 10,347 square foot suite spanning 75 and 79 Holly Court to create adequate workflow and operations. A single semi-automated outpatient pharmacy processing operations line will be installed, which will be used by licensed pharmacists and pharmacy techs to process outpatient pharmacy orders. A number of related renovations and upgrades will also be made as part of the project, including, for example, reconfiguring existing modular workstations, constructing a staff breakroom and wellness room, adding a conference

room, constructing a shipping and receiving area to support deliveries and shipments, upgrading mechanical HVAC systems, and performing electrical upgrades. The Holly Court property is owned by UVMMC and the project will require no tenant relocation. *See* App., 4-6.

- 8. The total capital expense for the project is \$5,810,888, which includes approximately \$3.4 million in facility renovations and upgrades, \$2.4 million in equipment costs, and \$29,000 in capitalized interest. LOI, 2. The equipment that will be purchased and installed as part of the project includes a Parata single semi-automated outpatient pharmacy operations line that will automate dispensing activities that are now physically organized manually and completed in a software queue. The production line and two Parata Max+ robotic dispensing machines will physically organize the work in order of priority and route each task to the right person along the line, resulting in a highly efficient dispensing process that can accommodate a much higher volume with significantly lower labor input than would otherwise be required. In selecting the equipment, the applicant consulted with Vanderbilt University Medical Center's pharmacy organization and compared several options that are compatible with UVMMC's software and operations. The same Parata equipment that was chosen for the project is currently used by almost all academic health system specialty and mail order pharmacy operations nationwide. App., 7-8.
- 9. The project also includes a minor redesign of the existing retail pharmacy on the first floor of the UHC facility. Currently, the retail pharmacy is supported by ground floor pharmacy processing operations in the same location. With processing operations moving to Holly Court, the existing pharmacy would be unsupported. To allow UVMMC to maintain a small retail presence at the UHC location to serve University of Vermont staff and students on campus, including patients of UVM's student health center, the applicant intends to add a nominal pharmacy processing operation within the first-floor retail space. The applicant plans to add a non-automated pharmacy processing line, drug storage and vaccination space, and perform only minimal mechanical, electrical, and plumbing updates. App., 6.
- 10. All proposed renovations, including existing and new support and circulation areas, have been reviewed to ensure regulatory compliance with the 2018 Edition of the Facility Guidelines Institute (FGI) guidelines. App., 6.
- 11. The UHC facility cannot support the applicant's pharmacy volume projections and is therefore ill suited for the co-location of the network's outpatient pharmacy operations. The UHC facility cannot accommodate the automated drug dispensing equipment included in the project, which will modernize operations and increase dispensing capacity. App., 3-4.
- 12. The applicant rents the UHC facility pursuant to a lease that expires in 2024. Based on this factor and the need for a larger, more appropriate space to house operations that will meet current and projected pharmacy volumes, the UVMMC Master Facility Plan includes relocation of all pharmacy dispensing activities now performed in the lower level (basement) of the UHC location. App., 4.

- 13. The project will be completed in five phases with construction beginning in July 2022 and lasting approximately 26 weeks. *See* App., 1, 6. There will be no interruption in outpatient pharmacy prescription. LOI, 2; App., 14.
- 14. The applicant will work with Efficiency Vermont to ensure that only energy efficient design systems and products are selected for the project. The proposed mechanical HVAC equipment will use the best available technology to reduce energy consumption and provide a comfortable environment. The project will utilize energy efficient LED lighting to meet general illumination requirements. *See* App., 12.
- 15. The project will enable the applicant to meet its volume projections without needing to hire additional FTEs. The project will utilize a high-speed production line, including conveyor belts between each workstation and two dispensing robots that will count pills and capsules, place them into vials, and label the vials, which will then move throughout the dispensing process in totes tracked with radio-frequency identification tags. The vials will be routed to the appropriate workstation based on the indicated stage of workflow. The automated process will increase efficiency and streamline pharmacy operations. App., 9.
- 16. UVMMC asserts that the project will not drive any increased volume and will allow it to support growth projections driven by other initiatives. App., 2, 11; Resp. (Dec. 15, 2021), 6. UVMMC anticipates that the percentage of outpatient prescriptions that are 340B eligible will not change as a result of the project. App., 2.
- 17. Overall pharmacy staffing will not be reduced because of the project. The applicant estimates that it would take an additional five to six staff, in a very large space, to achieve the same results as the automated environment it seeks to develop with the project. The applicant has assumed a savings of five FTEs over a five-year period, starting with one FTE savings in the first year and building to a savings of five FTEs in the fifth year. App., 10.
- 18. The applicant expects to use available working capital in fiscal years 2022 and 2023 to fund the project, without the need for borrowing. App., 13.
- 19. The staffing costs that the applicant expects to avoid with the project are not included in the project cost. App., 10. A cash flow analysis presented by the applicant shows a positive cash flow in the second year of operation due to the avoided staffing costs and shows the project breaking even in just over five years. App., 10-11, 13; Resp. (Dec. 15, 2021), 6. While the project generates a small incremental revenue loss over the first five years (-\$102,773), the applicant expects the outpatient pharmacy services division will continue generating a positive margin to offset the loss. App., 11; Resp. (Dec. 15, 2021), 6.
- 20. The project was included in UVMMC's fiscal year 2021 capital budget submission to the Green Mountain Care Board and in UVMMC's fiscal year 2022 budget detail submitted in August 2021. App., 1.

Standard of Review

Vermont's CON process is governed by 18 V.S.A. §§ 9431-9446 and Green Mountain Care Board Rule 4.000 (Certificate of Need). An applicant bears the burden of establishing that a CON should be granted. GMCB Rule 4.000, § 4.302.3.

Conclusions of Law

I.

Under the first statutory criterion, an applicant must show that the proposed project aligns with statewide health care reform goals and principles because the project takes into consideration health care payment and delivery system reform initiatives; addresses current and future community needs in a manner that balances statewide needs (if applicable); and is consistent with appropriate allocation of health care resources, including appropriate utilization of services, as identified in the Health Resource Allocation Plan (HRAP). 18 V.S.A. § 9437(1).

The project aligns with statewide health care reform goals and principles and addresses current and future community needs. The project will enable the applicant to meet projected growth in outpatient pharmacy demand that is being driven by increases in mail order and specialty pharmacy, expansion of the Health Assistance Program (HAP), and increasing enrollment in UVMHN's self-funded health care plan. Findings of Fact (Findings) ¶ 3. The HAP enables low-and middle-income patients to obtain medications at no cost, thereby promoting medication compliance. *See* Findings, ¶ 4. The UVMHN self-funded health plan's pharmacy program offers employees low-cost benefits and incentives such as zero-dollar copays for generic prescriptions when filled by the UVMMMC pharmacy. *See* Findings, ¶ 5. The project will enable increased patient access to prescription drugs through these two programs, which can lead to better health outcomes, reduced utilization of health care services, and lower cost, consistent with the goals and principles of health care reform.

The project is also consistent with the HRAP,¹ which identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. Relevant HRAP standards are 1.3 (to the extent neighboring health care facilities provide the services proposed by a project, a collaborative approach to delivering services has been taken or is not feasible or appropriate); 1.9 (costs and methods of proposed construction are necessary and reasonable and cost effective and reasonable energy conservation measures have been taken), 1.10 (projects requiring construction are energy efficient and Efficiency Vermont, or an organization with similar expertise, has been consulted), 1.12 (projects involving new construction comply with the FGI guidelines), 3.4 applicants subject to budget review must show that proposed project was included in hospital budget submissions or explain why inclusion was not feasible). *See* Findings, ¶¶ 1-2, 6, 10, 14, 18-19.

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¹ The Vermont legislature in Act 167 (2018) made several changes to the State's CON law. *See* https://legislature.vermont.gov/assets/Documents/2018/Docs/ACTS/ACT167/ACT167%20As%20Enacted.pdf. As amended by Act 167, 18 V.S.A. § 9437(1)(C) continues to reference the HRAP, which is in the process of being updated. In the interim, we consider the current HRAP standards.

Based on the information above, we conclude that the applicant has met the first criterion.

II.

Under the second statutory criterion, an applicant must demonstrate that the cost of the project is reasonable because the applicant's financial condition will sustain any financial burden likely to result from completion of the project and because the project will not result in an undue increase in the costs of medical care or an undue impact on the affordability of medical care for consumers. In considering whether the project will have an undue impact on the cost or affordability of medical care, the Board must consider and weigh relevant factors, such as "the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures and charges [and whether such impact] is outweighed by the benefit of the project to the public." Under the second statutory criterion, the applicant must also demonstrate that less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate; and, if applicable, that the project has incorporated appropriate energy efficiency measures. 18 V.S.A. § 9437(2).

The applicant has demonstrated it can sustain any financial burden likely to result from completion of the project. The applicant expects to use available working capital in fiscal years 2022 and 2023 to fund the project, without the need for borrowing. Findings, \P 18. The project will break even in just over five years and will produce a positive cash flow in its second year of operation. *See* Findings, \P 19.

The applicant has demonstrated that the project will not result in an undue increase in the costs of medical care or an undue impact on the affordability of medical care for consumers. The project it will enable the applicant to efficiently meet growth in demand that is being driven by factors such as the expansion of the HAP and UVMHN's self-funded health care plan, both of which will increase the ability of certain patients to access prescription drugs at lower costs. Findings, ¶¶ 3-5, 15.

The applicant has demonstrated that less expensive alternatives are not satisfactory or are not feasible or appropriate. The applicant's existing facility at UHC is leased and cannot accommodate the equipment needed to automate operations. Findings, \P 11-12. The project will utilize space that the applicant already owns and which can be renovated to house both outpatient mail order and specialty pharmacy processing operations, which are already located on the premises. Findings, \P 7.

Lastly, the applicant has demonstrated the project has incorporated appropriate energy efficiency measures. The applicant stated that it will work with Efficiency Vermont to ensure that only energy efficient design systems and products are selected for the project. The proposed mechanical HVAC equipment will use the best available technology to reduce energy consumption and provide a comfortable environment. The project will also utilize energy efficient LED lighting to meet general illumination requirements. Findings, ¶ 14.

We conclude that the applicant has satisfied the second criterion.

Under the third criterion, an applicant must demonstrate that "there is an identifiable, existing, or reasonably anticipated need for the proposed project that is appropriate for the applicant to provide." 18 V.S.A. § 9437(3).

The applicant has satisfied the third criterion. The applicant's outpatient pharmacy volumes are projected to substantially increase over the next several years, driven by growth in mail order and specialty pharmacy demand, expansion of the HAP, and increased enrollment of employees in the network's self-funded health plan, and the applicant's existing facilities, as currently configured, are inadequate to meet the growing demand. Findings, ¶¶ 4, 11. The project will allow the applicant to meet the growing demand by consolidating outpatient pharmacy dispensing services and automating operations using highly efficient processing equipment. Findings, ¶ 15. Because UVMMC already has contracts in place to provide these services, which support initiatives across the network, it is appropriate that UVMMC meet this need.

IV.

The fourth criterion requires that an applicant demonstrate that the proposed project will improve the quality of health care in Vermont, provide greater access to health care for Vermonters, or both. 18 V.S.A. § 9437(4).

The project will enable the applicant to meet projected demand for mail order and specialty drugs into the future. Findings, $\P\P$ 3, 15. Two of the drivers of the growth in outpatient pharmacy demand – expansion of the HAP and extension of pharmacy benefits to employees through the expansion the network's self-funded health plan – are aimed at broadening access. *See* Findings, $\P\P$ 3-5.

We find that the applicant has met this criterion.

V.

The fifth criterion requires that an applicant demonstrate that the project will not have an undue adverse impact on any other services it offers. 18 V.S.A. § 9437(5).

The project will not have an adverse impact on any other services that UVMMC offers. There will be no tenant relocation at the Holly Court site, which already houses outpatient specialty pharmacy operations, and UVMMC will retain limited retail pharmacy at UHC to serve UVM staff and students, including patients of UVM's student health center. Findings, ¶¶ 6, 9. There will be no interruption in outpatient pharmacy prescription dispensing operations. Findings, ¶ 13.

We find that this criterion has been satisfied.

VI.

The sixth criterion was repealed, effective July 1, 2018. Act 167 (2018), § 6.

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VII.

The seventh statutory criterion requires that an applicant adequately consider the availability of affordable, accessible transportation services to the facility, if applicable. 18 V.S.A. § 9437(7). This criterion is not applicable to this project as UVMMC will continue to offer limited retail pharmacy services at UHC and there will be no retail presence at the Holly Court site. Findings, ¶ 6.

VIII.

The eighth statutory criterion states that if the application is for the purchase or lease of new Health Care Information Technology, it must conform to the Health Information Technology Plan. 18 V.S.A. § 9437(8). As the project does not involve the lease or purchase of a new Health Care Information Technology, this criterion is not applicable.

IX.

Finally, the ninth criterion requires that an applicant demonstrate that the proposed project will support equal access to appropriate mental health care that meets standards of quality, access, and affordability equivalent to other components of health care as part of an integrated, holistic system of care, as appropriate. 18 V.S.A. § 9437(9).

UVMMC asserts that this criterion is not applicable to this project. We conclude that, to the extent the criterion is implicated, it is satisfied. The project will support expansion of programs that are aimed at increasing access to needed outpatient drugs of all kinds at a low cost, regardless of the nature of patients' conditions. See Findings, \P 3-5.

Conclusion

Based on the above, we conclude that the applicant has demonstrated that it has met each of the required statutory criterion under 18 V.S.A. § 9437. We therefore approve the application and issue a certificate of need, subject to the conditions outlined therein.

SO ORDERED.

Dated: April 1, 2022, at Montpelier, Vermont.

s/	Kevin Mullin, Chair	_)	
)	GREEN MOUNTAIN
s/	Jessica Holmes		CARE BOARD
)	OF VERMONT
s/	Robin Lunge	_)	
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s/	Tom Pelham	_)	
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s/	Thom Walsh)
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Filed: April 1, 2022

Attest: Jean Stetter, Administrative Services Director

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